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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,116	01/24/2002	Todd K. Whitehurst	AB-165U	1864
23845	7590	12/23/2005	EXAMINER	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

10/057,116

Applicant(s)

WHITEHURST ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The indicated allowability of claims 1-11 and 15-22 is withdrawn in view of the Schulman et al. reference listed below. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-11 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al. (WO 98/37926) in view of Novak et al. (the article entitled: "Outcome Following Implantation of a Peripheral Nerve Stimulator in Patients with Chronic Nerve Pain").

Regarding claim 1, Schulman discloses providing at least one leadless stimulator (100) having at least two electrodes (112a and 112b), implanting the at least one stimulator adjacent to at least one nerve (see col. 2, lines 16-23), at least in part responsible for sensations in a region experiencing pain (note col. 3, lines 30-34); providing operating power to the at least one stimulator (see text abridging cols. 3 and 4), using at least one external appliance to transmit stimulation parameters to the at least one stimulator (col. 5, lines 5-8), receiving and storing the stimulation parameters (col. 5, lines 5-28), generating stimulation pulses in accordance with the stimulation parameters (col. 5, lines 1-4), and delivering the stimulation pulses to nerves adjacent to the at least one stimulator (see col. 6, lines 59-63), wherein the stimulator has a size and shape suitable for placement of the electrodes adjacent to the at least one peripheral nerve (see col. 6, lines 55-57).

Although Schulman et al. do not explicitly discuss a method for treating *chronic* pain, Schulman et al. teach that the device may be used to treat pain in general (see

col. 3, lines 30-36). It is further taught that a rechargeable battery may be employed in those applications requiring longer treatment times due to the recurring nature of the ailment (note for example col. 4, lines 40-56 and col. 11, lines 2-16). Novak et al. further teach that chronic pain can be successfully treated with a peripheral nerve stimulator (see the last paragraphs on pages 1969 and 1971). Given the fact that one of the intended uses of the Schulman et al. device is to treat pain via nerve stimulation, and given the teaching that the implant may be powered indefinitely from an external power source depending on the particular application at hand, with the treatment of chronic pain by peripheral nerve stimulators known, those of ordinary skill in the art presented with a patient experiencing chronic pain, would have seen the obviousness of utilizing the method of Schulman et al. to block chronic pain and provide a measure of relief to the patient.

Regarding the step of identifying a patient experiencing sensations of chronic peripheral pain, it is axiomatic that Schulman et al. must identify a patient experiencing pain if they intend to use the device to treat pain as disclosed. Novak et al. further teach that successful pain relief depends upon accurate patient selection.

Regarding the limitation concerning peripheral nerves, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation – especially in view of the teachings of Novak et al.. The type of pain to be treated and the physiology of the nervous system would naturally dictate where the most effective application site resides.

Regarding claims 2 and 3 and claims with similar limitations, note the pulse parameters listed in Table I (col. 7).

Regarding claim 4 and claims directed to specific nerves or chronic pain locations, as reasoned above, because the device of Schulman et al. with its relatively small size is capable of being placed in virtually any region of the body that may require nerve stimulation treatment, and because Schulman does not limit his method to any

one nerve in particular, it would have been obvious to implant the device near a peripheral nerve if the peripheral nerve required stimulation.

Regarding claim 9 and claims directed to details of the sensor, note the text abridging cols. 7 and 8.

In regards to claim 10 and similarly worded claims, Schulman shows in Fig. 2 a diagram of the stimulator containing a sensor 188 coupled to the stimulation electrodes.

Regarding claim 15, comments paralleling those made in the rejection of claim 1 apply here as well.

Concerning claim 21, note the text abridging cols. 7 and 8.

Regarding claim 22, Schulman disclose that glucose—a blood borne substance—may be sensed (text abridging cols. 7 and 8).

Response to Arguments

4. Applicant's arguments with respect to claims 1-11 and 15-22 have been considered but are moot in view of the new ground(s) of rejection.

The applicant should note that the above §103 rejection is a rejection based on a §102(b) reference. The conditions of §103(c)(1) are not met.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

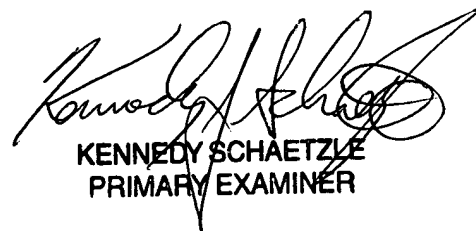
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS

December 5, 2005



KENNEDY SCHAEETZLE
PRIMARY EXAMINER